UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,972	04/16/2003	Myun K. Han	P 0265292	8011

909 7590 09/26/2005

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
MCLEAN, VA 22102

EXAMINER	
LEWIS, AMY A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,972	HAN ET AL.	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A&B*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Case

The Preliminary Amendment, filed 26 December 2001, has been entered into the application. Accordingly, the specification has been amended to include International Application data.

Applicant's claim for the benefit of a prior-filed application 09/339,813, filed 25 June 1999, under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

1) Claims 1-18 and 21-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not reasonably provide enablement for treatment or prevention of viral infection with the claimed active agents and conjugates thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The burden of enabling the prevention of a condition such as a viral infection, including HIV (of instant claims 8, 15, and 37) would be much greater than that of

enabling the treatment of the condition. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing a viral infection or how a patient could be kept from every being susceptible to this condition. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active agents for preventing viral infections.

The term "prevention" is synonymous with the term "curing" and both circumscribe methods of absolute success. Since absolute success is not reasonably possible with most diseases/conditions, especially those having etiologies and pathophysiological manifestations as complex as viral infections, the specification, which lacks an objective showing that viral infections, an more specifically HIV, can actually be prevented, is viewed as lacking an adequate written description of the same.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) Nature of the invention.
2) State of the prior art.
3) Relative skill of those in the art.
4) Level of predictability in the art.
5) Amount of direction or guidance provided by the inventor.
6) Presence or absence of working examples.
7) Breadth of the claims.
8) Quantity of experimentation necessary to make or use the invention based on the content of the disclosure.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1) The nature of the invention.

The claimed invention relates generally to chemotherapy, and specifically to compositions and methods for treating or preventing a viral infection without regard to the environment which includes both *in vitro* and *in vivo*. In addition, the claimed invention related to treating *all* viruses in general (see instant claims 1, 11, and 37).

2) State of the prior art.

While the state of the art is relatively high with regard to the treatment of specific types of viruses, for example herpesvirus or influenzavirus, the state of the art with regard to treating and preventing viruses in general is underdeveloped. In particular, there is no known antiviral agent that is effective against all viruses. The Goodman & Gilman reference (Goodman & Gilman's, "The Pharmacological Basis of Therapeutics 10th Edition, Hardman and Limbard, Editors, 2001, McGraw-Hill Co., Inc. Publisher; Chapters 50 & 51, pages 1313-1380) clearly shows that for the various known viruses, there is no one specific chemotherapeutic agent that is effective for all types of viruses. See: Table 50-2 at page 1315; Table 50-3 at page 1317 (regarding herpesvirus agents); Table 50-4 at page 1329 (regarding influenzavirus agents); Table 50-5 at page 1338; and Table 51-7 at page 1373 (regarding retrovirus agents).

In addition, regarding HIV, there is no known pharmacological method of

preventing infection, and standard antiretroviral treatment involves multiple agents belonging to several different classes of antiretroviral agents. (See: Goodman & Gilman's Chap. 51).

3) Relative skill of those in the art.

The relative skill of those in the art is high, generally that of a PHD and/or MD with several years of practical experience.

4) Level of predictability in the art.

The viral treatment art involves a very high level of unpredictability as demonstrated by the state-of-the-art with regard to the treatment of specific viruses with specific agents and has long been underdeveloped with regard to the treatment of viruses broadly (see discussion in section *2)* above on the state of the prior art). The lack of significant guidance from the present specification or prior art with regard to the actual treatment of all types of viruses in a mammal, including a human subject, with the claimed active ingredients makes practicing the claimed invention unpredictable.

In addition, the level of unpredictability is especially high regarding the treatment of HIV (see instant claims 8, 15, and 37). Many HIV infected patients are non-responsive, develop drug resistance or experience severe adverse effects to anti-retroviral therapy (See Goodman & Gilman's Chap. 51: abstract, p. 1351-1352 § General Principles of Antiretroviral Therapy).

5) Amount of direction or guidance provided by the inventor & 6) Presence or absence of working examples.

The Examples described in the instant specification are essentially drawn

to *in vitro* assays against HIV-1 integrase (not the actual HIV virus), and an *in vivo* cell culture model of FIV. This does not describe or enable the prevention or treatment of any virus in general.

The specification teaches HIV-1 integrase inhibition activity of "Fraction 1," obtained from *Salvia* genus plant extracts, as demonstrated in an *in vitro* assay (See specification Example 2, page 38+). The specification does not specify which type of *Salvia* plant was used to obtain the extract (it is presumably *Salvia miltiorrhiza* or "SY", which is not defined, see specification p. 30 Example 1). Also, the assay was run using "Fraction 1" of the column, which is not a **specifically defined** instantly claimed compound.

The specification teaches treatment of FIV using the *Salvia miltiorrhiza* extract "Fraction 1" in an *in vitro* cell culture assay using CrFK cells (see Example 3, pages 40-43).

The specification teaches anti-HIV-1 intergase activity with "various conjugations of 'Compound 1'" (See Example 5, pages 46-49). It is not clear by the description of Example 5, or any other examples, what was actually tested in this assay, or what the "various conjugates" are specifically comprised of.

7) Breadth of claims.

The claims are extremely broad and inclusive of all viruses generally. The breadth of the claims exacerbate the complex nature of the subject matter to which the present claims are directed. The claims are extremely broad due to the vast number of possible viruses represented by the phrase "treating or preventing a viral infection."

The claims are also extremely broad and inclusive of any combination of conjugates of *Salvia* genus compounds. Even where conjugates were tested, it is not clear what the specific conjugate was comprised of (see discussion in sections *5)* and *6)* above).

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification does not enable any person skilled in the art to which it pertains (i.e. antiviral therapy and prevention or treatment of viruses) to make or use the invention commensurate in scope with the claims. The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all viruses with the claimed *Salvia* genus agents fails to rebut the presumption of unpredictability existent in this art. Applicants fail to provide the guidance and information required to ascertain which particular type viruses the claimed antiviral agent will be effective against without resorting to undue experimentation. Applicant's limited disclosure with respect to anti-HIV-1 integrase activity and FIV with Compound 1 and conjugates of Compound 1 (see specification Examples 2-4, and 7) is noted but does not demonstrate treating or preventing all types of viruses.

Absent a reasonable *a priori* expectation of success for using a specific chemotherapeutic agent to treat any particular type of virus, one skilled in the art would have to extensively test many various viruses. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and

those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as it is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Written Description:

2) Claims 37-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for *Examination of Patent Applications* Under the 35 U.S.C. 112.1 "Written Description" Requirement ("*Guidelines*"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics *when coupled with a known or disclosed correlation between function and structure...*" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d, 316,

1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Claim 37 generally cites "a conjugation product according to claim 20," with claim 20 being directed to a method of identifying antiviral agents from the plant genus *Salvia*." There is insufficient descriptive support for said compounds. When functional claims are drawn this broadly, they are inclusive of *any* compound that may be identified using the method of instant claim 20. The instant specification does not describe all compounds identified by the method of claim 20. Additionally, Applicants describe only a limited number of compounds extracted from the plant *Salvia miltiorrhiza*, not from all plants in the genus. In accordance with the above-cited case law, Applicant's recitation of "a conjugation product according to claim 20," with claim 20 being directed to a method of identifying antiviral agents from the plant genus *Salvia*" is nothing more than a "wish or plan" for obtaining future compounds. Accordingly, the instant specification fails to provide an adequate written description of conjugation products obtained from the *Salvia* genus generally, and the specification as filed fails to provide any criteria by which a person of ordinary skill in the art could determine whether a given compound/conjugate is suitable for practicing the instantly claimed method.

M.P.E.P. § 2163 recites, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive

means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." Claims 5 and 13 are broadly drawn to a method comprising contacting p53- and S100-expressing cells (claim 5) and a method for treating cancer (claim 13) with any compound that can be identified by the method of claims 1 or 3. This group of compounds, however, is broad and diverse, and the specification as filed fails to provide any criteria by which a person of ordinary skill in the art could determine whether a given compound is suitable for practicing the instantly claimed method without actually performing the method of withdrawn claims 1 and 3.

M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus...when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. **For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**" According to applicants' disclosure,

over 1 million compounds were subjected to the screening methods of claims 1 and 3, of which 50 were found to bind S100 (page 49, paragraph 1). Applicant has failed to provide structures for each and every one of these 50 compounds, and no homology among said compounds is described such that the skilled artisan could immediately determine whether a given compound fulfills the requirements for the instantly claimed method.

Applicant claims a broad genus of compounds that must be presumed to comprise substantial variation, since the few specifically described compounds (see pages 50 and 51, section (a) of Example 7) have diverse structures. Some of the compounds are carboxylic acids (for example, compound 31) while others are amides (compound 3). Some compounds are halogenated (for example, compound 1), while others are not (for example, compound 38).

It is noted that some of the compounds of Example 7 are analogs of pentamidine, but applicant has failed to provide structures for the compounds that were not identified by the screen of Example 7. In short, applicant has failed to provide a comprehensive description of ALL of the compounds suitable for the method of claim 5, because no common characteristics of encompassed and excluded compounds are provided in the specification as filed.

The claims are currently in means-plus-function form; M.P.E.P. § 2163 teaches that such claims are adequately described if "the written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a step-plus-function claim limitation", or if "it is clear based on the facts of the

application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means-plus-function limitation", in this case the ability to be identified by the screening methods of withdrawn claims 1 and 3. The instant disclosure does not meet either of these criteria. As detailed above, the specification does not link any specific compound to the claimed activity, and because of the diversity of the genus of compounds able to be identified by the screening methods of withdrawn claims 1 and 3, the skilled artisan would not be able to determine which compounds do or do not perform the claimed function without extensive experimentation.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3) Claims 21-25 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in reference to the molecular weight of the conjugation product in these claims is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear

measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP § 2173).

Because the term "about" would invite subjective interpretations of whether or not a particular molecular weight or compound is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4) Claims 1, 2, 4, 7-9, 18, and 37-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Fesen MR, et al. ("Inhibitors of human immunodeficiency virus integrase," 1993 *PNAS*, Vol. 90: pages 2399-2403).

Fesen et al. describe the role of integrase in the HIV-1 virus life cycle (see introduction paragraph). Fesen et al. teach an *in vitro* assay of HIV-1 integrase function for screening potential inhibitors of the HIV integrase. The investigators found that caffeic acid phenethyl ester was the only compound that inhibited the integration step to a

substantially greater degree than the initial cleavage step of the integrase enzyme. (See: abstract; p. 2401 Fig. 5 Compound 23; Figures 1 & 2.)

5) Claims 1-4, 7, 8, 11-16, 18, 21, 22, 23 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kashiwada Y, et al. ("Anti-AIDS agents 18. Sodium and potassium salts of caffeic acid tetramers from *Arnebia euchroma* as anti-HIV agents," March 1995 *J Natural Products* 58(3): pages 392-400).

Kashiwada et al. teach caffeic acid tetramers (Kashiwada cited compounds 8 and 9) demonstrated potent anti-HIV activity in infected H9 cells (p. 398, Table 3). Kashiwada also teach a method of making (extraction, isolation, and various methylation processes) the caffeic acid compounds (see p. 398-399).

Regarding molecular weight of the conjugation product, caffeic acid (molecular weight =180, applicant specification p.31) tetramers would have a molecular weigh of 720, and compound 8 ($C_{36}H_{29}O_{16}$) specifically has a molecular weight of 717, thus meeting the instant limitation of a molecular weight of about 492-984.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6) Claims 43-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashiwada Y, et al. ("Anti-AIDS agents 18. Sodium and potassium salts of caffeic acid tetramers from *Arnebia euchroma* as anti-HIV agents," March 1995 *J Natural Products* 58(3): pages 392-400), in view of Li L ("Water soluble active components of *Salvia meltiorrhiza* and related plants," 1997 *J of Chinese Pharmaceutical Sciences*, 6(2): 57-64).

Kashiwada it applied as above. Specifically the reference teaches caffeic acid tetramers. Again, regarding molecular weight of the conjugation product, caffeic acid (molecular weight =180, applicant specification p.31) tetramers would have a molecular weigh of 720, and compound 8 ($C_{36}H_{29}O_{16}$) specifically has a molecular weight of 717, thus meeting the instant limitation of a molecular weight of about 492-984. the reference does not teach caffeic acid derived from *Salvia* species.

Li discloses Salvianoic acid compounds from *S. meltiorrhiza*. Li teaches that the genus *Salvia* contains more than one hundred species of plant and that studies on several of these species, including *Salvia meltiorrhiza*, yield various polyphenolic acids. These acids included caffeic acid dimers, rosemarinic acid, and several different salvionic acid

compounds. See: abstract; p. 58; Fig 1 on page 59; Table on page 60. The reference does not disclose anti-viral activity of the compounds or tetramers of the compounds.

It would have been obvious to one of ordinary skill in the art to make the anti-viral caffeic acid tetramers using salvianolic acid (of the plant *Salvia meltiorrhiza*), having been taught by the prior art (e.g. Li) that salvionolic acid, caffeic acid and dimmers thereof can be obtained from the plant *Salvia meltiorrhiza*, and motivated by the desire to obtain a source of salvionolic acid.

Pertinent Prior Art:

- Abd-Elazem IS, et al., "Isolation of two highly potent and non-toxic inhibitors of human immunodeficiency virus type 1 (HIV-1) integrase from *Salvia miltiorrhiza*", *Antiviral Res.* 2002 Jul; 55(1): 91-106.
- US Patent No. 5,178,865. Relevant to claims 1-18, 20-42. The patent is directed to Chinese herb extracts, including *Salvia* species that inhibit HIV infection in human T-lymphocytes.
- US Patent No. 5,411,733 teaches the antiviral (including herpes virus and HIV) of crude drugs obtained from various plant species, including *Salvia m.* Relevant to claims 1-18, 20-42.

Conclusion

Claims 1-59 are rejected. No claims are allowed.

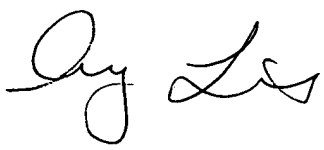
Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614



Christopher Low
SPE
Art Unit 1614